Early Detection and Early Intervention of Idiopathic Pulmonary Fibrosis

Company
Industry: Diagnostic/Therapeutic
Founded: Summer 2016
Facilities: Aurora, CO
Joint Venture: Vertex Pharm for drug discovery (11/2018)

Technology
Developed at University of Colorado Anschutz Medical Campus from the Schwartz/Yang laboratory

Financial Info
Business Stage: Pre-Clinical
Grants Contribution: $54M

Deal Structure
Series Seed: $10M
Soft-Circled: $5M

Scientific Team
IPF: David Schwartz, MD
Mucus Biol: Chris Evans, PhD
Biomarkers: Ivana Yang, PhD
Clinical Coor: Julie Powers, MPH

Chief Officers
► CEO: Bruce Schroffel, MPH
► CSO: David Schwartz, MD

Technology Overview
Genetic/Biomarker Diagnostic Screening Tool for Early IPF Detection

Value Proposition
► Promising in-vivo Results
► Early Stage Detection
► Early Stage Treatment
► Potentially Curative
► Largest IPF Case Dataset

Investor Attractions
►Orphan Disease Indication
►Rapid and Fatal Disease
►$1.1B Diagnostic Market
►$4.1B Therapeutic Market
►Early Revenue Opportunity
►No competitors focused on early disease
►Large exit opportunities with multiple active strategics

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Business Focus: Eleven P15 aims to sell a genetic/biomarker test that enables early detection of asymptomatic idiopathic pulmonary fibrosis, improves the success of human clinical trials, and plans to develop therapeutic solutions for early intervention.

Unsolved Problem: Idiopathic Pulmonary Fibrosis (IPF) is a chronic, fibrosing interstitial pneumonia of unknown cause, occurring primarily in older adults. IPF is a fatal disease with median survival at 3-5 years. Only two drugs have been approved but fail to reverse damaged lung function. Accurate diagnosis of IPF is also very challenging. In a national IPF survey, 42% endured a year or more between first experienced symptoms and diagnosis; 55% were misdiagnosed at least once.

Disruptive Technology: Eleven P15 is uniquely positioned for early detection and early intervention of IPF. The pivotal discovery of a common polymorphism in the promoter of *MUC5B* (rs35705950) has been associated with IPF and pulmonary fibrosis associated with rheumatoid arthritis, and this polymorphism increases the production of mucus. Findings from the Schwartz laboratory suggest that dysregulated *MUC5B* expression in the lung is involved in the pathogenesis of pulmonary fibrosis and it is now known to also be associated with survival in IPF. These findings form the basis of the diagnostic and therapeutic targets exploited by Eleven P15. Dr. Schwartz has also developed a Global IPF Network with ~50 international investigators and has amassed a collection of ~5,000 IPF cases. This IPF dataset is unparalleled in its scope and ability to expand our collective knowledge in pulmonary fibrosis.

Competition: While there exist several clinical approaches to treating IPF, few therapeutics have been clinically proven to provide significant benefit to patients. Only 2 therapeutics with specific indications for the treatment of IPF, pirfenidone (Esbriet) and nintedanib (Ofev), have been FDA approved. These only slow disease progression but are not curative. There are 9 therapeutics in the clinical development pipeline, but are all focused on established disease. Diagnostically, only Veracyte and VolitionRx are attempting to develop a diagnostic molecular classifier for IPF and are still in development.

Growing Market Opportunity: There are an estimated 2M individuals at risk of IPF disease globally in 2016. The diagnostic market in the 6 major markets for IPF is estimated at $1.1B by 2020. Total global revenues for approved IPF therapies Esbriet and Ofev were $900M in 2015 and projected to grow to $4.1B by 2020.

Regulatory: IPF is classified as an orphan disease. Eleven P15 diagnostic tools will initially be utilized in numerous clinical trials to accelerate late stage therapeutic targets while simultaneously identifying lead candidates for treatment in the early stage disease.

Achievements: Proof-of-concept in vivo animal testing; patent pending technology; first customers lined up to use diagnostic test in clinical trial stratification.

Future Milestones: Validate human biomarkers, Recruit seasoned executive management team, Demonstrate success of novel screened test drugs in animal models of pulmonary fibrosis, Perform phase I/II trial with mucolytic treatment in patients with IPF.

Key Scientific Members: David Schwartz, MD, has garnered a reputation as a pioneer in the field of genetics and epigenetics during his 30+ year career, having published more than 300 papers exploring the interface between genes and environment. As director of the National Institute of Environmental Health Sciences from 2005-2008, he spearheaded the creation of the $750M Epigenomics Roadmap Initiative. Schwartz and his colleagues discovered the common variant of a gene that codes for mucus production in IPF disease. He currently serves as Chair of the Department of Medicine at the University of Colorado. **Chris Evans, PhD,** is a professor at the University of Colorado and has worked with Dr. Schwartz for 7 years. Dr. Evans has expertise in mucin biology and biochemistry. **Ivana Yang, PhD,** is a professor at the University of Colorado and has worked with Dr. Schwartz for 15 years. Dr. Yang has extensive experience in understanding how genetics and transcriptomics affect human disease.

Assets:
1) 4 issued/pending patents
2) 3 seminal publications in the New England Journal of Medicine
3) Joint venture with Vertex Pharmaceuticals to develop MUC5B targeted drugs

Exit Strategy: Phase II acquisition of lead therapeutic candidate by large strategic such as Bristol-Meyers Squibb, Gilead, or GSK. Exits at this stage are typically $500M+.